510(k) Summary

K123754

510(k) Premarket Notification
CX50 Diagnostic Ultrasound System with Additional Indications

DEC 21 2012

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Penny Greco
Philips Healthcare, Inc.
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810-6302
Tel: (978) 659-4615
Fax (978) 975-7324

Date prepared: November 27, 2012

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Diagnostic ultrasound system and transducers

Proprietary Name: CX50 Diagnostic Ultrasound System
Classification: Class II

21 CFR Section	Classification Name	Product Code
892.1550	System, Imaging, Pulsed Doppler, Ultrasonic	90 IYN
892.1560	System, Imaging, Pulsed Echo, Ultrasonic	90 IYO
892.1570	Transducer, Ultrasonic, diagnostic	90 ITX

3) Substantially Equivalent Devices

Philips Healthcare CX50 Diagnostic Ultrasound System	K111513
Philips Healthcare HD11 Diagnostic Ultrasound System	K062247
Philips iU22 (formerly known as Boris)	K030455

3) Device Description
The CX50 Diagnostic Ultrasound System is a compact, AC or battery powered, 128 –channel, cardiac ultrasound imaging system. It uses custom digital electronic and fabrication technologies to provide diagnostic ultrasound information and is housed in a portable, laptop-style chassis.

The subject of this submission is the addition of new indications to Philips CX50 ultrasound system and the transducers that employ the new indications. The new indications include: ICE (intracardiac echo), Intraoperative, and Laparoscopic.

- The ICE indication employs St. Jude Medical's ViewFlex Xtra catheter (K121381). This indication is equivalent to that of Philips HD11 which supports the intracardiac echo indication and use of St. Jude Medical's ViewFlex ICE catheters (K062247/K121381).

- The Intraoperative indication employs the L15-7io and the C9-3io. The L15-7io was cleared for use with the Philips iU22 (formerly known as Boris, K030455). The C9-3io is similar to the L15-7io, but curved rather than linear.

- The laparoscopic indication employs the L10-4lap transducer that is equivalent to the L9-5lap cleared for use with the Philips iU22 (formerly known as Boris, K030455).

4) Intended Use

The CX50 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical –mode), Pulse Wave Doppler, continuous Wave Doppler, color Doppler, tissue Doppler Imaging and Harmonics (Tissue and contrast) modes. The device is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esophogeal. (Cardiac), Peripheral Vessel, Other (Carotid).

5) Technological comparison to predicate devices

With the implementation of the new indications CX50 employs the same technology as the HD11 with intracardiac echo and the iU22 with intraopertive and laparoscopic indications. The devices all use digital electronic and fabrication technologies to provide diagnostic ultrasound information. The CX50 is a Track 3 system that employs the same fundamental scientific technology as the iU22 and HD11.

6) Determination of Substantial Equivalence

Non-clinical performance data

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance
- IEC 60601-1-1: Medical Electrical Equipment - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993: Biological evaluation of medical devices.

Quality assurance measures applied to the system design and development include, but were not limited to:

- Rick Analysis
- Product Specifications
- Design Reviews
- Verification and Validation

Summary of Clinical Tests

This release of CX50 introduces no new indications for use, modes, features, or technologies relative to the predicate devices (HD11, K062247, and iU22, K030455) that require clinical testing. The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

7) Conclusions

CX50 with additional indications is substantially equivalent in safety and effectiveness to the predicates identified above:

- The predicate devices and CX50 with additional indications are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate devices and CX50 with additional indications have the same gray-scale and Doppler capabilities.
- The predicate devices and CX50 with additional indications use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate devices and CX50 with additional indications have acoustic output levels within the Track 3 FDA limits.
- The predicate devices and CX50 with additional indications are manufactured under equivalent quality systems.
- The predicate devices and CX50 with additional indications are manufactured of materials with equivalent bio safety. The materials have been evaluated and found to be safe for this application.
- The predicate devices and CX50 with additional indications are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards
There are no Sec. 514 performance standards for this device.

Prescription Status
This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)
Not applicable. No components supplied sterile.

Track
This is a Track 3 system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Philips Ultrasound, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO NY 55313

Re: K123754
Trade/Device Name: CX50 3.0 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 4, 2012
Received: December 6, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CX50 3.0 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

S5-1	X7-2t	C10-3v
C9-3v	L12-3	L15-7io
C5-1	C8-5	C9-3io
D5cwc	S8-3	L10-4lap
D2cwc	S12-4	Medical ViewFlex Xtra
	L12-5 50	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Mr. Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): k123754

Device Name: Philips CX50 Diagnostic Ultrasound System

Philips CX50 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Ophthalmic
Intraoperative
Laparoscopic
Fetal
Abdominal
Pediatric
Small Organ
Adult Cephalic
Neonatal Cephalic
Trans-vaginal
Musculo-skeletal
Gynecological
Cardiac Adult
Cardiac Pediatric
Trans-Esoph. (Cardiac)
Intracardiac echo
Peripheral Vessel
Other (Carotid)

The clinical environments where the CX50 Diagnostic Ultrasound System can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Janine M. Morris -S
2012.12.21 16:56:42 -05'00'

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric	P	P	P	P	P	P	P (1,3-8)
	Abdominal	P	P	P	P	P	P	P (1,3-9)
	Intraoperative (vascular/epicardial)	N	N	N		N	N	N (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic	N	N	N		N	N	N (1,3,4,5,7)
	Pediatric	P	P	P		P	P	P (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	P	P	P		P	P	P (1,3-8)
	Neonatal Cephalic	P	P	P	P	P	P	P(1-8)
	Adult Cephalic	P	P	P	P	P	P	P (1,3-7)
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P (1,3-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	P	P	P		P	P	P (1,3-8)
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult	P	P	P	P	P	P	P(1-4)
	Cardiac Pediatric	P	P	P	P	P	P	P (1-7)
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P(1-4)
	Other (Intracardiac)	N	N	N	N	N	N	N (1-7)
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P (1,3-8)
	Other (Carotid)	P	P	P		P	P	P (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue or Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 for CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:56:15 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754`

Device name: S5-1 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	P	P	P		P	P	P (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	P	P	P	P	P	P	P (1-8)
	Adult Cephalic	P	P	P	P	P	P	P (1,3-7)
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P (1-7)
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: C9-3v transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	P	P	P		P	P	P (1,3-8)
	Abdominal	P	P	P		P	P	P (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: C5-1 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	P	P	P		P	P	P (1,3-8)
	Abdominal	P	P	P		P	P	P (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P (1,3-9)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)	P	P	P		P	P	P (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P (1,3-8)
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: D5cwc transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric				**P**			**P (1-7)**
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel				**P**			
	Other (Carotid)				**P**			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: D2cwc transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

* Other modes:
Combined modes:
Previous submission: K111513 CX50

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:54:04 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: X7-2t transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	**P**	**P**	**P**	**P**	**P**	**P**	**P (1-6)**
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 CX50	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:53:39 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: L12-3 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	P	P	P		P	P	P (1,3-8)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	P	P	P		P	P	P (1,3-8)
	Neonatal Cephalic	N	N	N		N	N	N (1-8)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	P	P	P		P	P	P (1,3-8)
	Musculo-skel (superficial)	P	P	P		P	P	P (1,3-8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P (1,3-8)
	Other (Carotid)	P	P	P		P	P	P (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K111513 for CX50 previously cleared indication (shown as N above); L12-3 transducer and other indications (P) cleared K091804	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:53:13 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: C8-5 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N (1,3-8)
	Abdominal	N	N	N		N	N	N (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,3-8)
	Neonatal Cephalic	N	N	N		N	N	N (1-8)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1,3-8)
	Musculo-skel (superficial)	N	N	N		N	N	N (1,3-8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N (1,3-8)
	Other (Carotid)	N	N	N		N	N	N (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:52:48 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: S8-3 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N	N	N	N	N (1-4,6)
	Abdominal	N	N	N	N	N	N	N (1-4,6)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1-4,6)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	N	N	N	N	N	N	N (1-4,6)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1-4,6)
	Musculo-skel (superficial)	N	N	N		N	N	N (1-4,6)
	Other (Gynecological)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N (1-4,6)
	Cardiac Pediatric	N	N	N	N	N	N	N (1-4,6)
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:52:24 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: S12-4 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N	N	N	N	N (1-4,6)
	Abdominal	N	N	N	N	N	N	N (1-4,6)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1-4,6)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic	N	N	N	N	N	N	N (1-4,6)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N (1-4,6)
	Cardiac Pediatric	N	N	N	N	N	N	N (1-4,6)
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio Imaging 6. 3D Imaging 7. SonoCT 8. Biopsy guidance 9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:50:32 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: L12-5 50 transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N (1,4,6,7,8)
	Abdominal	N	N	N		N	N	N (1,4,6,7,8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1,4,6,7,8)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,4, 6,7,8)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1,4,6,7,8)
	Musculo-skel (superficial)	N	N	N		N	N	N (1,4,6,7,8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac echo)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N(1,4,6,7,8)
	Other (Carotid)	N	N	N		N	N	N (1,4,6,7,8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio Imaging 6. 3D Imaging 7. SonoCT 8. Biopsy guidance 9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:50:07 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: C10-3v transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N (1,3-8)
	Abdominal	N	N	N		N	N	N (1,3-9)
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	N (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: The C10-3v is a renamed C9-3v (K111513 for CX50)	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: L15-7io transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)	N	N	N		N	N	N (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,3,4,5,7)
	Neonatal Cephalic	N	N	N		N	N	N (1,3,4,5,7)
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1,3,4,5,7)
	Musculo-skel (superficial)	N	N	N		N	N	N (1,3,4,5,7)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N (1,3,4,5,7)
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3: iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: C9-3io transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	N	N	N		N	N	N (1,3,4,5,7)
	Intraoperative (vascular/epicardial)	N	N	N		N	N	N (1,3,4,5,7)
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,3,4,5,7)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:47:28 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: L10-4lap transducer for use with CX50 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic	N	N	N		N	N	N (1,3,4,5,7)
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac echo)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:** 1. Harmonics (Tissue & Contrast) 2. Tissue Doppler Imaging 3. iSCAN 4. X-Res	5. Angio Imaging 6. 3D Imaging 7. SonoCT 8. Biopsy guidance 9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

Janine M. Morris -S
2012.12.21 16:47:03 -05'00'

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: k123754

Device name: St. Jude Medical ViewFlex Xtra (K121381)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intraoperative (vascular/epicardial)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Intracardiac)	N	N	N	N	N	N	N (1-7)
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Carotid)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics

Prescription Use (Per 21 CFR 801.109)

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